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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,254	07/14/2003	Steven W. Dow	2880	9736

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EXAMINER

HOLLERAN, ANNE L

ART UNIT      PAPER NUMBER

1643

DATE MAILED: 09/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/621,254	<b>Applicant(s)</b> DOW ET AL.	
	<b>Examiner</b> Anne L. Holleran	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on 26 June 2006.
- 2a)  This action is **FINAL**.
- 2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 1-23,31-121 and 143-150 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) \_\_\_\_\_ is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claim(s) 1-23,31-121 and 143-150 are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All    b)  Some \*    c)  None of:
    - 1.  Certified copies of the priority documents have been received.
    - 2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    - 3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5)  Notice of Informal Patent Application (PTO-152)
- 6)  Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. The response to the restriction requirement mailed 4/26/2006 is acknowledged.

However, upon further consideration, a new restriction is set forth.

#### ***Election/Restrictions***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 52-59, drawn to composition comprising a ligand for pattern recognition family of receptors, which ligand comprises a GLYCOPROTEIN derived from any portion of a bacterial pathogen, fungal pathogen, organism, virus, rickettsial organism, parasitic organism or arthropod, classified in class 530, subclass 395.
- II. Claims 52-59, drawn to composition comprising a ligand for pattern recognition family of receptors, which ligand comprises a LIPOPROTEIN derived from any portion of a bacterial pathogen, fungal pathogen, organism, virus, rickettsial organism, parasitic organism or arthropod, classified in class 530, subclass 359.
- III. Claims 52-59, drawn to composition comprising a ligand for pattern recognition family of receptors, which ligand comprises a CARBOHYDRATE derived from any portion of a bacterial pathogen, fungal pathogen, organism, virus, rickettsial organism, parasitic organism or arthropod, classified in class 536, subclass 1.11.
- IV. Claims 52-59, drawn to composition comprising a ligand for pattern recognition family of receptors, which ligand comprises a LIPID derived from any portion of a bacterial pathogen, fungal pathogen, organism, virus, rickettsial organism, parasitic organism or arthropod, classified in class 424, subclass 283.1.

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- V. Claims 52-59, 60-62, and 104-107, drawn to composition comprising a ligand for pattern recognition family of receptors, which ligand comprises a NUCLEIC ACID derived from any portion of a bacterial pathogen, fungal pathogen, organism, virus, rickettsial organism, parasitic organism or arthropod, classified in class 536, subclass 22.1.
- VI. Claims 52-59, 102 or 103, drawn to composition comprising a ligand for pattern recognition family of receptors, which ligand comprises a PROTEIN OR PEPTIDE SEQUENCE derived from any portion of a bacterial pathogen, fungal pathogen, organism, virus, rickettsial organism, parasitic organism or arthropod, classified in class 530, subclass 300 or 350.
- VII. Claims 44-46, 98 and 99, drawn to a composition comprising a ligand for pattern recognition family of receptors, which ligand comprises a PORTION OF A BACTERIUM, classified in class 424, subclass 234.1.
- VIII. Claims 47-49, 108 and 109, drawn to a composition comprising a ligand for pattern recognition family of receptors, which ligand comprises a PORTION OF A FUNGAL ORGANISM, classified in class 424, subclass 274.1.
- IX. Claims 50, drawn to a composition comprising a ligand for pattern recognition family of receptors, which ligand comprises a PORTION OF A MULTICELLULAR ORGANISM, classified in class 424, subclass 520.
- X. Claims 51, drawn to a composition comprising a ligand for pattern recognition family of receptors, which ligand comprises a PORTION OF A UNICELLULAR ORGANISM, classified in class 424, subclass 93.1.

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- XI. Claims 9, 10, 86, 87, 112-121, drawn to methods of treating cancer comprising administering a composition comprising a pattern recognition receptor ligand, unclassified because classification depends on the classification of the ligand.
  - XII. Claims 11, 12, 88, 89, drawn to methods of treating infections disease, comprising administering a composition comprising a pattern recognition receptor ligand, unclassified because classification depends on the classification of the ligand.
  - XIII. Claims 13-15, drawn to methods of treating allergic disease comprising administering a composition comprising a pattern recognition receptor ligand, unclassified because classification depends on the classification of the ligand.
  - XIV. Claims 16-22, drawn to methods of treating autoimmune disease comprising administering a composition comprising a pattern recognition receptor ligand, unclassified because classification depends on the classification of the ligand.
  - XV. Claims 143-145, drawn to methods of bone healing comprising administering a composition comprising a pattern recognition receptor ligand, unclassified because classification depends on the classification of the ligand.
  - XVI. Claims 146-150, drawn to methods of relieving injury comprising administering a composition comprising a pattern recognition receptor ligand, unclassified because classification depends on the classification of the ligand.
3. Claims 1-8, 23 and 83-85 link inventions XI-XVI. Claims 31-42, 63-70, 77-82 link inventions I-X. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims, claims 1-8, 23 and 83-85 or claims 31-42, 63-70, 77-82.

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Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicant is advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims in the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. The inventions are distinct, each from the other, for of the following reasons:

Each of inventions I-X is drawn to a composition comprising a separate and distinct product. In the case of group I, the product is a glycoprotein, which encompasses a separate and distinct class of molecules from the products of group II, lipoprotein; the products of group III, carbohydrates; the products of group IV, lipids; the products of group V, nucleic acids; the products of group VI, protein or peptide sequence; the products of group VII, portions of bacteria; the products of group VIII, portions of fungal organisms; the products of group IX, portions of multicellular organisms; and the products of group X, portions of unicellular organisms. Each of the products has a different classification in the US Patent classification system, and each of these products encompasses a separate and distinct genus of molecules that would require a separate search in the non-patent literature. Furthermore, the search in the patent

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and non-patent literature would not be limited to the products in the context of the intended use of the products or by the function of binding to a particular receptor.

Therefore, it would impose an undue burden on the examiner to have to search and examine any of inventions I-X together, because the search for each of the invention groups would not be coextensive and involves search of generic classes of products.

Inventions XI and any of XII, XIII, XIV, XV and XVI are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are distinct because each of the inventions is directed to the treatment of a separate class of disease. In the case of invention XI, the class of disease is cancer, which is a separate and distinct class of disease from infectious diseases; or from allergic diseases; or from autoimmune diseases; or from diseases of bone; or from injury. Treatment for each of these diseases encompasses methods that have a different effect. In the treatment of cancer the endpoint may be inhibition of tumor growth or eradication of a tumor; in treatment of infectious disease the endpoint is to rid the host of the infectious agent; in the treatment of allergic diseases the endpoint is to alter the response of the immune system to external antigens; in the treatment of autoimmune disease the endpoint is to alter a malfunctioning of the immune system in distinguishing self from non-self; in the treatment of diseases of the bone, the endpoint is to affect bone growth or response to a bone graft; and in the treatment of injury the endpoint is to alleviate symptoms associated with oxidative injury or apoptotic injury that may occur in

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response to a primary mode of treatment. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Therefore, it would impose an undue burden on the examiner to have to search and examiner any of inventions XI-XVI together, because the search for each of the invention groups would not be coextensive and involves searches of separate and distinct classes of disease processes.

Inventions I-X, and XI-XVI are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the compositions of any of inventions I-X appear to be useful for generally stimulating an immune response to a specific antigen in addition to having use in methods of treatment of diseases of inventions XI-XVI. Additionally, the processes of treatment of diseases such as cancer, infectious disease, allergy, autoimmune disease, bone healing or treatment of injury may be practiced with another materially different product from the products of any of inventions. Thirdly, each of the diseases of invention groups XI-XVI represents a separate and distinct process of using the claimed products of invention groups I-X.

Furthermore, it would impose an undue burden on the examiner to have to search and examiner any of inventions XI-XVI together with any of inventions I-X, because the search for each of the invention groups would not be coextensive and involve a search for the products that is not limited by the intended use of the claimed products.



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Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

***Species Election:***

If any of inventions I-X is elected then a further election of species is required.

This application contains claims directed to the following patentably distinct species:

**I. species of antigen:**

- a) viral organism
- b) bacterial organism
- c) fungal organism
- d) protozoan organism
- e) parasitic pathogen
- f) rickettsial organism
- g) arthropod organism
- h) protein or peptide molecule
- i) carbohydrate molecule
- j) a lipoprotein molecule
- k) a glycopeptide molecule
- l) a glycolipid molecule
- m) a lipid molecule

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n) a non-tumor cell

o) a tumor cell

The species are independent or distinct because they are drawn to independent and distinct organisms, molecules or cells.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 69-72 and 77-82 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

If any of inventions XI-XVI is elected then a further election of species is required.

This application contains claims directed to the following patentably distinct species:

**II. species of ligand:**

a) glycoprotein

b) lipoprotein

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- c) glycolipid
- d) carbohydrate
- e) lipid
- f) nucleic acid
- g) protein or peptide sequence
- h) portion of a bacterium
- i) portion of fungus
- j) portion of a multicellular organism
- k) portion of a unicellular organism

The species are independent or distinct because they are drawn to independent and distinct classes of molecule or organism.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1-23, 83-89, 112-121 and 143-150 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an

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allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran  
Patent Examiner  
September 7, 2006



**LARRY R. HELMS, PH.D.**  
**SUPERVISORY PATENT EXAMINER**